

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE LANTUS DIRECT PURCHASER  
ANTITRUST LITIGATION

Civil Action No. 16-12652-LTS-JGD

**DEFENDANTS' OBJECTION TO THE REPORT AND RECOMMENDATION  
CONCERNING STATE ACTION IMMUNITY  
ON PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT**

## INTRODUCTION

Judge Dein correctly concluded that there are genuine issues of fact as to whether Sanofi-Aventis U.S. LLC (“Sanofi US”) exercises management control over Sanofi-Aventis Puerto Rico, Inc (“Sanofi PR”). Doc. No. 418 (“R&R”) at 48-49. But she also expressly acknowledged one key *undisputed* fact—that the Puerto Rico Department of Consumer Affairs (DACO) exercises pricing control over Lantus products sold in Puerto Rico at all relevant times—that should have led her to reject *as a matter of law* the ownership or control exception to the *Illinois Brick* direct purchaser rule that Plaintiffs urged her to apply.

An antitrust plaintiff can only sue a defendant for overcharges under federal law if the plaintiff purchased products *directly* from that defendant. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 736-40 (1977). Plaintiffs’ Motion seeks to circumvent the direct purchaser rule by invoking an exception that applies only if the defendant owns or controls the entity from which the plaintiff purchased the product subject to the alleged overcharge, and set the prices along the chain of distribution. *See* Doc. No. 326 (“Opp.”) at 7. Plaintiffs assert that Sanofi US controls Sanofi PR and supplied it with Lantus<sup>®</sup> products, which Sanofi PR then sold in Puerto Rico at prices set by Sanofi US. Accordingly, Plaintiffs argue, any entity that purchased Lantus products from Sanofi PR can sue Sanofi US for alleged overcharges supposedly passed through Sanofi PR to customers in Puerto Rico.<sup>1</sup>

But it is undisputed, as Judge Dein recognized, that DACO—not Sanofi US or Sanofi PR—set the prices at which Sanofi PR sold Lantus products in Puerto Rico at all relevant times. As

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<sup>1</sup> Judge Dein also correctly recommended granting Sanofi PR’s separate motion for summary judgment on grounds that it is not part of a single economic enterprise with Sanofi US, in particular because Sanofi PR did not participate in the Orange Book listing and litigation conduct that allegedly allowed Sanofi US to delay competition, and thereby maintain higher prices, for Lantus. R&R at 49, 60-67. Thus, the only basis Plaintiffs have for challenging Puerto Rico sales of Lantus is the theory that Sanofi US controlled the prices at which Sanofi PR sold Lantus, thereby enabling Sanofi US to pass on the inflated prices to customers of Sanofi PR.

such, the control exception should have been rejected as a matter of law for two reasons. *First*, because DACO is a state agency, state-action immunity bars Plaintiffs' claims as to purchases in Puerto Rico. *Second*, the control exception to *Illinois Brick* cannot apply where an independent third party controls the price that the indirect purchaser pays. For each of these reasons, the Court should adopt Judge Dein's recommendation to deny Plaintiffs' motion, but should do so on the additional, and dispositive, ground that DACO's control over Lantus prices in Puerto Rico precludes this action by Puerto Rico purchasers as a matter of law.

## ARGUMENT

### I. STATE ACTION IMMUNITY BARS PLAINTIFFS' PUERTO RICO PURCHASE CLAIMS.

When a state regulator acting pursuant to state policy sets or approves sales prices, private parties are immune from antitrust liability for sales made at those prices. *S. Motor Carriers Rate Conf., Inc. v. United States*, 471 U.S. 48, 57 (1985); *see also Ports Auth. of P.R. v. Compañía Panameña de Aviación (Copa), S.A.*, 77 F. Supp. 2d 227, 233 (D.P.R. 1999) (applying state-action immunity to private party because a Puerto Rican agency set the rate for a challenged airport fee).

Two elements are required for state-action immunity to apply. *First*, the legislature must “clearly articulate[] and affirmatively express[]” the regulatory authority to displace competition with price regulation. *Ports Auth.*, 77 F. Supp. 2d at 233. *Second*, the government must “actively supervise[]” the price-setting activity, meaning that a government agency must affirmatively approve the final prices charged. *Id.*; *see also Mass. Furniture & Piano Movers Ass’n, Inc. v. FTC*, 773 F.2d 391, 394 (1st Cir. 1985) (state must intend to “displace competition” with regulation, and must “actively supervise[]” the prices set by private parties).

Both elements are readily satisfied here. For state authorization, the Puerto Rico Legislature has expressly enacted a policy to displace competition with regulation by authorizing DACO to “fix, control, freeze and review the prices ... on the goods, products and those services

... which are offered or sold in Puerto Rico.” P.R. Laws Ann. tit. 3, § 341e(a). *See* Opp. 17. And, since September 2014, DACO has actively supervised pricing by requiring Sanofi PR to submit all proposed Lantus price changes to DACO for approval, and affirmatively setting Lantus prices in Puerto Rico. *See* Opp. 18.

Judge Dein acknowledged that DACO undisputedly “had the final authority to determine the sale price” for Lantus prices in Puerto Rico, and that “before Sanofi P.R. could implement a change to the [price] for any Lantus product sold in Puerto Rico, it had to submit the proposed change to DACO for review.” R&R 22-23. But she nevertheless rejected state-action immunity because the “plaintiffs are not defining the anticompetitive conduct as the setting of prices for Lantus.” R&R 47-48. Instead, she concluded, plaintiffs define the relevant anticompetitive conduct as listing patents in the FDA’s Orange Book and suing on those patents, and DACO does not “regulate the listing of patents in the Orange Book or the initiation of patent infringement litigation.” R&R 48. That analysis is inapposite to the ownership and control exception to the *Illinois Brick* direct purchaser rule that Plaintiffs urge here.

Plaintiffs’ indirect-purchaser claim for Puerto Rico sales depends *entirely* on a theory that Sanofi US controlled the price of Lantus products sold in Puerto Rico. Specifically, Plaintiffs assert that Sanofi US set inflated prices for Lantus products, sold those products to Sanofi PR, and then, by controlling the price at which Sanofi PR sold Lantus products to the Puerto Rico purchasers, passed-on the inflated prices through Sanofi PR to the Puerto Rico purchasers. *See* Doc. No. 309 (“Mem.”) at 8, 13. Consequently, *how* the price of Lantus is set in Puerto Rico is the relevant conduct for purposes of assessing Defendants’ state-action immunity arguments.

Indeed, courts routinely apply separate immunity analyses to separate types of conduct. *AT&T v. IMR Capital Corp*, 888 F. Supp. 221 (D. Mass. 1995), a case Judge Dein repeatedly cited,

illustrates this very point. There, the plaintiff asserted a monopolization claim and alleged multiple types of anticompetitive conduct by the same defendant, including price and non-price conduct (such as a refusal to provide certain types of phone equipment and services). *Id.* at 239-240. The court conducted a separate immunity analysis for each. *Id.* It granted immunity for the price-setting conduct because the government authorized and supervised those prices, but it refused to extend immunity to the non-price conduct because a government actor was not involved in those decisions. *Id.*

The same distinction applies here. Plaintiffs have alleged two types of conduct for which they seek to hold Sanofi US liable for sales of Lantus in Puerto Rico: the Orange Book listing and patent litigation in which Plaintiffs concede (and Judge Dein found, R&R 60-61) Sanofi PR played no role, *and* the alleged sale of Lantus by Sanofi PR at prices purportedly controlled by Sanofi US. As in *AT&T*, a government actor—DACO—undisputedly set the prices for Lantus products in Puerto Rico under authorization from the Puerto Rico legislature. DACO’s intervention creates immunity for Sanofi PR’s sales of Lantus at allegedly supracompetitive prices in Puerto Rico (i.e., the only conduct in which Plaintiffs allege Sanofi PR engaged), and the only basis upon which Plaintiffs seek to invoke the ownership and control exception to hold Sanofi US liable for Lantus sales by Sanofi PR in Puerto Rico.

Moreover, it makes sense to apply immunity here in light of the rationale for extending state-action immunity to private parties, which is to ensure that states can “implement programs that restrain competition among private parties” without interference from federal antitrust laws. *S. Motor Carriers*, 471 U.S. at 56. If immunity did not apply, “[a] plaintiff could frustrate any such program merely by filing suit against the regulated private parties.” *Id.* That is precisely what Plaintiffs seek to do here. They seek to “frustrate” Puerto Rico’s pharmaceutical price control

program “merely by filing suit against the regulated private parties” for selling pharmaceuticals at prices controlled by DACO under a state “program[] that restrains competition among private parties.” *Id.* Plaintiffs also rely on *In re New Mexico Natural Gas Antitrust Lit.*, 1982 WL 1827 (D. N.M. 1982), arguing that immunity does not apply “where a regulator merely ‘sets a ceiling on the price ... but does not require’” the defendant to sell at that price. Doc. No. 338 at 7 (quoting *New Mexico* at \*17). That case is inapposite because it was decided before, and conflicts with, *Southern Motor Carriers*, 471 U.S. at 59-60. There, the Supreme Court held that immunity applies to price setting where a state official affirmatively authorizes maximum prices, even if the state does not *compel* the defendants to sell at those prices. *Id.*; *see also Mass. Furniture & Piano Movers Ass’n, Inc. v. FTC*, 773 F.2d 391, 395 (1st Cir. 1985) (“state compulsion of private anticompetitive conduct is not required”). Under *Southern Motor Carriers*, it makes no difference whether DACO compelled Sanofi PR to sell at a certain price, so long as DACO authorized that price.

Finally, there is no basis for Plaintiffs’ fleeting suggestion that Defendants waived the DACO immunity argument by not including it in their Answer. *See* R&R 46, n.17 (“plaintiffs note but do not appear to rely on an argument that defendants waived the defense of state-action immunity”). DACO’s control of prices is the 20th defense in Sanofi PR’s Answer. Doc. No. 271 at 203 (“[T]he price of Lantus in Puerto Rico is controlled by the Puerto Rico Department of Consumer Affairs.”); *see also id.* at 200 (Fifth and Seventh Defenses); Doc. No. 270 (Sanofi US Answer) at 198 (reserving right to rely on any applicable defenses set forth in any other party’s answer); *id.* at 199 (Fifth and Seventh Defenses). This was more than sufficient to put Plaintiffs on notice and preserve the DACO defense.

**II. THE CONTROL EXCEPTION DOES NOT APPLY WHEN AN INDEPENDENT ACTOR CONTROLS THE INDIRECT-SALE PRICE.**

DACO's ultimate control over Lantus prices is crucial for a second reason: it means the control exception to *Illinois Brick* does not apply as a matter of law. As Judge Dein explained, the exception asks whether Sanofi US controlled Sanofi PR sufficiently to "set prices along the chain of distribution." R&R 39 (quoting *In re Vitamin C Antitrust Litig.*, 279 F.R.D. 90, 101 (E.D.N.Y. 2012)). Under the leading case on which Judge Dein relied, the exception must be "construed narrowly to apply only when the antitrust defendant has ... sufficient ... control over the intermediary sellers to set prices along the chain of distribution." *Kloth v. Microsoft Corp.*, 444 F.3d 312, 321 (4th Cir. 2006).

It is undisputed here—as Judge Dein acknowledged—that DACO has final control over the price of Lantus products in Puerto Rico. R&R 22-23. That single, undisputed fact is dispositive. Because DACO controlled Lantus prices, Sanofi US cannot possibly have exercised sufficient control over Sanofi PR to "set prices along the chain of distribution." *Kloth*, 444 F.3d at 321.

In concluding that the control question must be submitted to the jury, Judge Dein pointed to other facts, such as questions about Sanofi PR's board of directors, its management, and its finances. R&R 34-44. But those facts cannot make a difference under the applicable legal standard, which asks whether the defendant has requisite control over the prices set along the chain of distribution. In other cases, those types of veil-piercing facts might well serve as a useful proxy to assess the level of managerial control by one entity over another. But this is a unique case (and unlike any cited in the briefs) in which a government agency wields ultimate control over prices along the chain of distribution. In this context, DACO's control is dispositive.

To be clear, Judge Dein correctly rejected Plaintiffs' argument that they are somehow entitled to summary judgment because Sanofi US sets an initial wholesale price for Lantus products. R&R at 39. Whether Sanofi US sets an initial price is irrelevant because there is no dispute that: (1) DACO intervenes in Puerto Rico, (2) DACO has control of Lantus prices in Puerto Rico, (3) DACO publishes an approved final price for Lantus products in Puerto Rico, and (4) Sanofi PR always sold Lantus products at the price approved by DACO. Thus, while Judge Dein correctly recommended denial of summary judgment, the Court should also deny summary judgment on the additional and critical ground that the ownership or control exception cannot apply as a matter of law.

### **CONCLUSION**

For the foregoing reasons, the Court should deny Plaintiffs' motion for partial summary judgment on the grounds identified by Judge Dein and on the additional ground that the Puerto Rico purchasers are not proper plaintiffs as a matter of law.



Dated: August 31, 2022

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Theresa C. Martin, hereby certify that a true copy of the foregoing document filed through the ECF system will be electronically sent to the registered participants as identified on the Notice of Electronic Filing on August 31, 2022.

/s/ Theresa C. Martin  
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